

2723 '99 DECENVE

July 8, 1999

The Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C. Street S.W. Washington, DC 20204

## Dear Sir/Madam:

This is a notification pursuant to 21 U.S.C. 343(r)(6) that Standard Process Inc., Palmyra, Wisconsin 53 156-0904, is making the following statements:

- (1) The antigenic properties promote healthy cellular division, function, and growth.\*
- (2) The bovine ovary **PMG**<sup>TM</sup> extract in Ovatrophin PMG appears to neutralize the circulating antibody, thereby **contri** buting to the maintenance of cellular health. \*
- (3) Ovatrophin PMG improves calcium absorption.\*
- (4) Ovatrophin PMG sustains metabolic efficiency. \*
- (5) Maintains cellular health. \*
- (6) Magnesium and calcium play an important role in human metabolism.\*
- (7) Magnesium functions in **such** reactions as nerve conduction and nerve excitability; transfer of energy, muscular activity; and many other specific processes. \*
- (8) Magnesium functions as a co-factor, assisting enzymes in catalyzing many chemical reactions.\*
- (9) Ovatrophin PMG provides nutritional ingredients and support for the ovaries.\*

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These statements are made for a dietary supplement containing a proprietary blend of bovine ovary PMG<sup>TM</sup> extract and magnesium citrate. Other ingredients include calcium lactate, cellulose, and calcium stearate. And the name of the product is Ovatrophin PMG®.

The information contained herein is accurate and Standard Process Inc. has substantiation that the statements are truthful and not misleading.

Sincerely yours,

Ann Holden

Standard Process Inc.

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